HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 7 1999 '99 SEP 10 A9:33

Joseph Mendelson, III
Legal Director
Center for Food Safety
c/o International Center for Technology Assessment
310 D Street, NE
Washington, DC 20002

Docket 99P-0033

Dear Mr. Mendelson:

On August 5 you wrote the Commissioner, Food and Drug Administration, expressing a concern about the Agency failure to provide a timely response to Citizen Petition Docket No. 99P-0033. I am responding to your letter on behalf of the Commissioner and providing a tentative response as permitted under 21 CFR 10.30(e)(2)(iii).

Citizen Petition (CP) No. 99P-0033, received on January 7, 1999, seeks amendments to 21 CFR 589.2000. (Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, finalized at 62 FR 30936 June 5, 1997).

According to the administrative regulations at 21 CFR 10.30, the FDA is to respond to a CP within 180 days. In respect to CP 99P-0033, FDA is currently considering the issues raised, the many comments received to it, and the current scientific publications dealing with the spread of transmissible spongiform encephalophathies. Because of the complex nature of the action requested, which requires careful and thorough scientific, legal, and policy consultation, and analysis, FDA will require additional time to issue the final response.

FDA will issue the final response upon completion of our analysis of the CP, comments on it sent to the Docket, and the resolution of any scientific, legal, or policy issues.

Sincerely yours,

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Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

99P-0033

ANS1

cc:
HF-40
HF-22
GCF-1
HFA-305 99P-0033
HFV-1 OD#18
HFV-6
Gmitchell/ar/8/30/99
Final: JDawson/GMitchell/ar:09-01-99
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